PATENT

39994A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	:	
Glenn P. Vonk et al.	:	Confirmation No. 5157
Serial No.: 09/881,041	:	Group Art Unit: 3626
Filed: June 15, 2001	:	Examiner: Sereboff, Neal
For: A HEALTH OUTCOMES AND DISEASE MANAGEMENT NETWORK AND RELATED METHOD FOR PROVIDING IMPROVED PATIENT CARE	:	

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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Sir:

This is an appeal pursuant to 35 U.S.C. § 134 from the Examiner's decision rejecting claims 1-7 as set forth in the final Office Action of November 13, 2009 and further in Advisory Action mailed March 2, 2010.

I. Real Party in Interest

The real party in interest in this application and the appeal is Becton Dickinson and Company by an assignment recorded September 6, 2002 on Reel 013266, Frame 0424.

II. Related Appeals and Interferences

There are no other related patents or applications related to this invention on appeal or that are involved in an interference proceeding.

III. Status of Claims

Claims 1-7 are pending and are the subject of this appeal. Claims 1-7 stand finally rejected and are reproduced in the Claims Appendix (Section VIII). Claims 8 – 25 were canceled.

IV. Status of Amendments

Amendments to the claims were filed on September 25, 2009 in an Amendment and Request to Reopen Prosecution Following Decision on Appeal Pursuant to 37 C.F.R. 41.50(b)(1). The amendments to the claims were entered in the November 13, 2009 final rejection.

V. Summary of the Claimed Subject Matter

Briefly, the present invention is directed a health outcomes and disease management network and related method for providing improved healthcare. A network 102 of healthcare managers and healthcare providers 106 interactively cooperate with patients or clients 112 to enroll clients in the network with a plan of care, monitor and evaluate patient status to provide the most appropriate treatment for the patients in the most cost-effective manner, thus improving overall healthcare. Electronic assessment tools allow a health care provider 106 to

assess patient health-related data received from remote monitoring stations to determine progress of the patient on the selected treatment program and whether information needs to be conveyed to the patient in response to the progress determination. The information to be conveyed relates to the selected treatment program and is selected to advise the patient on how to improve the integration of the selected treatment program into the patient's lifestyle.

With reference to the originally filed application, independent claim 1 recites a system for monitoring health-related conditions of patients, comprising:

a plurality of remote monitoring stations (Fig. 1., 112, 114, ¶44), each being configured to receive patient health-related data pertaining to a respective patient; and

a computer network (Fig. 1, 102) comprising a database (Fig. 1, 104, ¶44, ¶46) containing accumulated health-related data pertaining to health-related conditions and treatments that reveals population trends and outcomes (¶3, ¶79), and at least one data access device configured to provide a health care provider (Fig. 1, 106, ¶44, ¶45) access to said computer network and said database, said computer network configured to receive said patient health-related data pertaining to respective patients from said remote monitoring stations and provide a health care provider with electronic treatment establishment tools (¶46, ¶¶90-92) to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data, and said computer network configured to revise said accumulated health-related data based on said patient health-related data for identification of improvements in standards of care and medical practices (¶29, ¶46, ¶79, ¶117, ¶120) that can be made for different ones of the health-related conditions;

said remote monitoring stations (Fig. 1., 112, 114) being configured with electronic self-management tools (¶25, ¶26, ¶71, ¶99) for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools;

said computer network (Fig. 1, 102) being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress

(¶76) of the patient on the selected treatment program and whether information, which relates to the selected treatment program and is selected to advise the patient on how to improve the integration of the selected treatment program into the patient's lifestyle, needs to be conveyed (¶78, ¶95) to the patient in response to said progress determination.

VI. Grounds of Rejection to be Reviewed on Appeal

The grounds of rejection for review on appeal are:

(a) whether claims 1-7 fail to comply with the written description requirement under 35 U.S.C. § 112, first paragraph;

(b) whether claims 1-7 fail to particularly point out and distinctly claim the subject matter which appellants regard as the invention under 35 U.S.C. § 112, second paragraph; and

(c) whether claims 1-7 are unpatenable under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,867,821 to Ballantyne et al (hereinafter "Ballantyne") in view of U.S. Patent No. 6,283,761 to Joao (hereinafter "Joao"), and further in view of U.S. Patent No. 5,937,387, to Summerell et al (hereinafter "Summerell").

VII. Arguments

Claim 1 recites, among other limitations, electronic assessment tools that allow a health care provider to assess patient data to determine (1) progress of a patient on a selected treatment program and (2) whether information needs to be conveyed to the patient in response to the progress determination. The information is recited as (1) relates to the selected treatment program; and (2) is selected to advise the patient on how to improve the integration of the selected treatment program into the patient's lifestyle.

A. Claims 1-7 comply with the Written Description Requirement Under 35 U.S.C. § 112, first paragraph

The Examiner rejects claims 1-7 under 35 U.S.C. § 112, first paragraph for allegedly lacking explicit, implicit, or inherent support in the specification for the claim recitation relating

to information which "relates to the selected treatment program" and "is selected to advise the patient on how to improve the integration of the selected treatment program into the patient's lifestyle" as recited in claim 1.

As stated in the Response to Final Office Action submitted on February 12, 2010 and repeated below, Appellants make citations to the originally filed specification as support for the claim language at issue. Accordingly, the claims 1-7 comply with 35 U.S.C. § 112, first paragraph. These citations to the originally filed specification correspond to paragraphs from the U.S. patent application published no. 2002/0072933 used in the Response to Final Office Action.

In the Advisory Action mailed March 2, 2010, the Examiner states that the citations made to the specification (i.e., to support the claim language "information...selected to advise the patient on how to improve the integration of the selected treatment program") do not "describe 'how to improve' but show potential areas of improvement."

Appellants traverse this is reasoning by the Examiner. The claim limitation in question is not directed to whether the patient uses the information or not, or actually improves or not, but rather to the information.

Briefly, as to the recited information, Appellants provide below citations from the specification that disclose (1) providing "treatment information and recommendations to the client" after monitoring client's status, and (2) providing "helpful health tips" to the client after the evaluation process 2100, and (3) whether, during the evaluation process 2100, information relating to the client's treatment program, medication, stress and activity, disease process, symptom management and nutrition should be conveyed to the client.

More specifically, Appellants respectfully direct the Examiner's attention to the following sections of the specification with references to the originally filed specification.

Paragraph [0051] describes using the system to determine progress of a patient on a selected treatment program. Paragraph [0075] describes an exemplary embodiment wherein progress is assessed by the system (e.g., client information in a database is analyzed to determine when physiological data from the client 112 corresponds to values outside normal limits).

> With reference to paragraph [0051], once a client is enrolled in a network, a healthcare manager develops a client plan of care (CPOC) and medical plan of care (NPOC) for the client 112 in cooperation with the care providers, such as the primary care physicians, hospitals and specialists (step 1200). In step 1300, the healthcare managers accordingly care for their respective clients 112 between the primary care

team and extended care teams, while also receiving, monitoring and evaluating information provided by the clients 112. During this time, the clients 112 are also responsible for monitoring and managing their conditions, and providing data to the centralized database 104. In step 1400, *the healthcare managers review the status of their respective clients 112 and compare their client's progress to expected outcomes.* The managers can coordinate with the care providers to revise the CPOCs and MPOCs for their respective clients 112, and report relevant information to the clients, PCTs, ECTs and payors, as necessary.

With reference to paragraph [0075], the healthcare manager tracks physiological data from the client 112 and responds to values outside the normal limits. The healthcare manager can contact the physician as appropriate with values outside the normal limits, and tracks the survey data provided by the client 112 in the SF-36, food diary, or a stress audit. The physician can respond the healthcare manager in a efficient and effective *manner regarding physiological parameters outside the desire limits, as appropriate. During this time, the centralized network 102 is receiving input of the data and using preset parameters to determine if the data is outside normal limits. The centralized network 102 notifies the healthcare manager of the data that is outside the limits*, and receives, stores and tracks the data provided by the client 112.

Paragraphs [0045], [0071], [0075], [0076], [0093] and [0095] describe how the claimed system provides patients with information that relates to a selected treatment program and is selected to advise a patient on how to improve integration of the treatment program into the patient's lifestyle in response to the above progress determination. As stated above in paragraph [0051], clients or patients 112 are responsible for monitoring and managing their conditions, and providing this information to the centralized database 104. Paragraph [0045], for example, describes how the system permits members of a care team to review the client information in the database and *provide treatment information and recommendations to the client.*

[0045] The clients 112 are provided with monitoring or diagnostic tools (e.g., blood pressure measuring devices 116, electronic scales 118, disease management information charts 120, and various other devices which can be used to obtain diagnostic and assessment information from the clients 112). The clients 112 use these tools to enter information about themselves and their condition into the centralized database 104 and then communicate personal information via their workstations 114. *Members of their care team 106 can review that information and monitor the clients' status as well as provide treatment information and recommendations to the client 112.*

As described in paragraph [0071], in step 1330, the client 112 executes self-management and self-education. That is, the client 112 integrates the MPOC and CPOC into his or her lifestyle consistently, while exploring and following self-education modules and asking questions during the regularly scheduled encounters with the healthcare manager. *The healthcare manager tracks client's responses to self-education modules, assesses the responses for consistent integration of CPOC and MPOC into the client's lifestyle.* With reference to paragraph [0075], during this activity, *the healthcare manager tracks physiological data from the*

client 112 and responds to values outside the normal limits. The healthcare manager can contact the physician as appropriate with values outside the normal limits, and tracks the survey data provided by the client 112 in the SF-36, food diary, or a stress audit. The physician can respond the healthcare manager in an efficient and effective manner regarding physiological parameters outside the desire limits, as appropriate. *During this time, the centralized network 102 is receiving input of the data and using preset parameters to determine if the data is outside normal limits. The centralized network 102 notifies the healthcare manager of the data that is outside the limits*, and receives, stores and tracks the data provided by the client 112. See also paragraph [0076], wherein the healthcare manager reviews the data from the client 112 regularly, evaluates whether the data is consistent with expected outcomes, and communicates with the client 112 regarding inconsistent outcomes. The data is archived and surveyed by the centralized network 102, which can send data messages from the client 112 to the healthcare manager for evaluation. *The client 112 also learns of ongoing evaluation and receives personal responses from the healthcare manager, as well as outcomes relating to the MPOC and CPOC.*

Paragraph [0093] describes a manager's evaluation process 2100. During the evaluation process, the manager determines in steps 2105, 2115 and 2125 whether individual client outcomes, generic standards and population outcomes, respectively, need to be evaluated and evaluates the outcomes as appropriate in steps 2110, 2120 and 2130, respectively. With reference to paragraph [0095], the manager's activity then proceeds to the education process in step 2200. *During the evaluation process, the manager determines in steps 2205, 2215, 2225, 2235, 2245 and 2255 whether information relating to the client's treatment program, medication, stress and activity, disease process, symptom management and nutrition, respectively, should be conveyed to the client 112.* If any of this information should be conveyed, the manager provides the information to the client 112 in steps 2210, 2220, 2230, 2240, 2250 and 2260, respectively, as appropriate. *The manager then determines in step 2265 whether helpful heath tips should be provided to the client 112 in step 2270.* The manager then reports the data obtained in the above steps to the centralized network 102, which can store the data in the centralized data base 104 as necessary.

Thus, the Appellants respectfully submit that the specification provides explicit support for information that relates to a selected treatment program and is selected to advise a patient on

how to improve the integration of the selected treatment program into the patient's lifestyle. Withdrawal of the 35 U.S.C. §112, first paragraph rejection of claim 1 is requested.

B. Claims 1-7 are Definite Under 35 U.S.C. § 112, second paragraph

The Examiner rejects claims 1-7 under 35 U.S.C. § 112, second paragraph for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellants regard as the invention. The Examiner points to the claim recitation "advise the patient on how to improve the integration" in claim 1 and states that "integration improvements are subjective" in the Final Office Action. The Examiner appears to be arguing that, if the integration improvements are subjective, then the claim is rendered indefinite "since it is not clear from the claim what the scope of the advice includes."

Appellants respectfully submit that the grounds stated for this rejection are improper and that the recitations relating to the claimed information (i.e., "selected to advise the patient...") should be given patentable weight. Accordingly, Appellants traverse the Examiner's rejection and submit that claim 1 is definite as written.

First, the claim does not recite "advice" per se as the Examiner contends in the Final Office Action. Claim 1 recites information that "relates to the selected treatment program" and "is selected to advise a patient on how to improve the integration of the selected treatment program into the patient's lifestyle." In other words, the information is selected to inform the patient on how to improve the integration.

Appellants submit that "to improve" the integration of a selected treatment program into one's lifestyle is readily discernible. As described above in connection with paragraphs [0045] and [0075] of the originally filed application, for example, the claimed system can determine client physiological data values that are outside normal limits and provide a client with treatment information and recommendations (e.g., to improve the physiological data values) in accordance with an exemplary embodiment. Further, with reference to the Deputy Commissioner for Patent Examination Policy (DCPEP) memorandum dated September 2, 2008, even if the claim term "to improve the integration" was not defined or used in the specification, it is discernible and hence not indefinite because "the components of the term have well recognized meanings, which allow

the reader to infer the meaning of the entire phrase with reasonable confidence". In other words, "improve" has a well recognized meaning.

Even if the recitation "to improve" the integration of a selected treatment program is arguably not precise, which Appellants do not concede, the fact that claim language may not be precise does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. See MPEP 2173.05(b). Appellants respectfully submit that one of ordinary skill in the art would understand what is claimed, in light of the specification, in view of at least paragraphs [0045] and [0075].

The Examiner also states in the Final Office Action that it is not clear from claim 1 "who or what advises the patient" and assumes that the "advice is performed by the health care provider." Appellants submit that the claim subsection in question recites a computer network configured with electronic assessment tools that determine whether information needs to be conveyed to the patient. Thus, it is the recited information that advises the patient once conveyed. Also, as stated above, claim 1 does not recite 'advice."

Finally, the Examiner states in the Final Office Action that the claim recitation is non-functional descriptive information with no patentable weight. Appellants disagree and respectfully submit that the recitation should be given patentable weight as it further limits "information" that is determined whether to be conveyed in response to the progress determination. Further, in its Decision on Appeal decided on July 28, 2009 (hereinafter "the Decision"), the Board of Patent Appeals and Interferences overruled earlier assertions that other recitations in claim 1 were not to be given patentable weight.

In the Advisory Action, the Examiner further states that Appellant arguments in the Response to Final Office Action submitted on February 12, 2010 fail to show how the 35 U.S.C. § 112, second paragraph is improper and, in further support of the rejection, asks how does a "human being...perform the required functionality in a way that could exclude others from making and using the invention." The Examiner also states that, since the actions of the "advise" may or may not be carried out or performed by another human being, the claim limitation "advise" has no patentable weight. Appellants disagree. The Examiner's inquiry of whether an

action is performed or not by another human being is immaterial. As stated above, claim 1 limitation in question is not directed to whether the patient uses the information or not, or actually improves or not, but rather to the information. The language in question (i.e., "selected to advise") further limits the recited "information" and therefore should be given patentable weight.

In view of the foregoing, withdrawal of the 35 U.S.C. §112, second paragraph rejection of claim 1 and its dependent claims 2-7 is respectfully requested.

C. Claims 1-7 are Not Obvious under 35 U.S.C. § 103(a) Over Ballantyne in view of Joao and further in view of Summerell

The claims 1-7 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,867,821 to Ballantyne et al (hereinafter "Ballantyne") in view of U.S. Patent No. 6,283,761 to Joao (hereinafter "Joao"), and further in view of U.S. Patent No. 5,937,387, to Summerell et al (hereinafter "Summerell"). In the Response to Arguments section of the final Office Action, the Examiner states "that it is not clear from the claim whether the information is directed to the patient or health provider." This is incorrect. Claim 1 recites "whether information, which relates to..., needs to be *conveyed to the patient*..." (emphasis added). Thus, the claim clearly recites that the information is directed to the patient.

The Response to Arguments section of the final Office Action also states "Therefore, the Appellant's arguments only potentially applicable [*sic*] if the claims are read through the Appellant's narrow review." First, Appellants submit that this statement is unclear. Nonetheless, this statement is inapplicable since the claim recites that the information is conveyed to the patient. Second, Appellants submit that this claim recitation was improperly ignored. Finally, Appellants respectfully submit that the Examiner has not fully responded to the following arguments, which were set forth in the Amendment and Response dated September 25, 2009.

Appellants respectfully submit that Joao does not teach or suggest the invention recited in claim 1.

On page 19 of the Decision, the Board relies on Joao (i.e., 27:58-67 and 28:38-60 as indicated in the Findings of Fact (FF) 16 on page 11 of the Decision) to purportedly teach the last

claim element of claim 1 directed to said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information needs to be conveyed to the patient in response to said progress determination.

The text referred to in FF16 (Joao 27:58-67) of the Decision does not mention reports. Thus, the Board relies on the evaluation report in FF16 (Joao 28:38-60) to purportedly teach the recited information in the last claim element of claim 1. The text referred to in FF16 (Joao 28:38-60), however, specifically refers to evaluating claims for payment. The evaluation report referred to at Joao 28:49-60 is merely for payment processing and indicates, at most, whether diagnoses and/or treatments are in-line with standards and should be paid or not.

The text at Joao 28:61-29:3 clearly states that a payer receives the evaluation report and not a patient. Appellants respectfully submit that the payer described in FF16 (Joao 28:38-60) is not the same entity as a patient. Even if the payer described in FF16 (Joao 28:38-60) were arguably assumed to be a patient, this assumption appears to be in contradistinction with the rest of Joao that specifically defines "patient" and 'payer" as different entities (see, for example the different definitions provided for "patient" and "payer" in Joao at 12:51-57 and at 13:8-19, respectively, and the separate listings of patients and payers in Joao such as at 2:22, 2:58 and 4:11-25.

In addition, Appellants submit that Joao fails to teach "...**determine progress** of the patient on the selected treatment program **and whether** information... **needs to be conveyed** to the patient... **in response to said progress determination**" (emphasis added) as recited in claim 1. Arguably, if an evaluation of report indicates denial of a claim, then the patient will be notified as such (e.g., perhaps by a denial report conveyed to the patient). Even if the evaluation report described in Joao 28:38-60 were arguably provided to a patient, the patient will at most learn that a claim for treatment has been denied or not for payment by the insurance provider. Appellants submit that evaluation of a treatment for insurance coverage is not a determination of progress of a patient on a selected treatment program as claimed. Also, a payer decision to pay a claim or not is not information selected to advise the patient on how to improve the integration of the selected treatment program into the patient's lifestyle as recited in claim 1.

Accordingly, withdrawal of 35 U.S.C. § 103(a) rejection of the claims 1-7 is respectfully requested.

D. Conclusion

For the reasons presented herein, Appellants submit that claims 1-7 comply with 35 U.S.C. §112, first and second paragraphs, and are not rendered obvious under 35 U.S.C. § 103(a) by the cited references of record. Accordingly, reversal of the final rejection is requested, and allowance of claims 1-7 is respectfully requested.

Respectfully submitted,

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Dated: May 13, 2010

VIII. CLAIMS APPENDIX

1. (Previously Presented) A system for monitoring health-related conditions of patients, comprising:

a plurality of remote monitoring stations, each being configured to receive patient health-related data pertaining to a respective patient; and

a computer network comprising a database containing accumulated health-related data pertaining to health-related conditions and treatments that reveals population trends and outcomes and at least one data access device configured to provide a health care provider access to said computer network and said database, said computer network configured to receive said patient health-related data pertaining to respective patients from said remote monitoring stations and provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data, and said computer network configured to revise said accumulated health-related data based on said patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions;

said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools;

said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information, which relates to the selected treatment program and is selected to advise the patient on how to improve the integration of the selected treatment program into the patient's lifestyle, needs to be conveyed to the patient in response to said progress determination.

2. (Previously Presented) A system as claimed in claim 1, wherein:

each of said remote monitoring stations comprises at least one measuring device, configured to measure a physiological condition of said respective patient, and to provide data representative of said physiological condition for inclusion among said patient health-related data; and

said electronic assessment tools are configured to allow a health care provider to monitor said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle and determine readiness of the patient for self-management under the selected treatment program.

3. (Previously Presented) A system as claimed in claim 1, wherein:

said remote monitoring stations are configured to provide said patient health-related data to said computer network over the Internet.

4. (Previously Presented) A system as claimed in claim 1, wherein:

said electronic assessment tools are selected from the group consisting of Standard Form-36 (SF-36), Duke Activity Index, guidelines of the Diabetes Quality Improvement Project (DQIP), tools for specific disease state monitoring, depression scales, nutrition assessment tools, quality of life assessment tools.

5. (Previously Presented) A system as claimed in claim 1, wherein:

said computer network is configured to generate reports, each including health-related information pertaining to a respective said patient.

6. (Previously Presented) A system as claimed in claim 1, wherein:

said computer network is configured to provide said accumulated health-related data stored in said database to organizations financing at least a portion of said treatment programs, and is configured to receive financial data pertaining to said treatment programs from said organizations and to store said financial data in said database.

7. (Previously Presented) A system as claimed in claim 1, wherein:

each said remote monitoring station receives from its respective said patient said patient health-related data including data pertaining to the cardiovascular system of said patient.

Claims 8 – 25 (Canceled)

IX. EVIDENCE APPENDIX

No evidence under 37 C.F.R. § 1.130, 1.131 or 1.132 is relied upon in this Appeal.

X. RELATED PROCEEDINGS APPENDIX

None